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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,275

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Shabtay Dikstein

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06/19/2008

NATH & ASSOCIATES
112 South West Street
Alexandria, VA 22314

EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

4161

MAIL DATE

DELIVERY MODE

06/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,275	Applicant(s) DIKSTEIN, SHABTAY	
	Examiner Sean Basquill	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the invention of Claim 21 and submission of new Claims 22-26 to the same method of treatment as that described in cancelled Claim 21 in the reply filed on April 2, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

2. Applicant's claims to the effective filing date of PCT Application PCT/IL2004/000747, filed 16 August 2004, is acknowledged.

3. The disclosure of the prior-filed application, Israeli application 157535, filed August 21, 2003 fails to provide adequate written support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the Israeli application makes no mention of topically applying testosterone phenyl propionate in a concentration range between 1% and 3% by weight of the total preparation, as recited in instant Claim 24. As such, the range of testosterone phenyl propionate concentration specified in instant Claim 24 will be provided only the priority date of the PCT application, 16 August 2004.

Claim Objections

4. Claim 22 is objected to because of the following informalities: "derivatives" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 23 recites the limitation “the method according to Claim 1.” Because there is no Claim 1, owing to the applicant’s cancellation thereof, there is insufficient antecedent basis for this limitation in the claim.

6. Claim 24 recites the limitation “the method according to Claim 2.” Because there is no Claim 2, owing to the applicant’s cancellation thereof, there is insufficient antecedent basis for this limitation in the claim.

7. Claim 25 recites the limitation “the method according to Claim 1.” Because there is no Claim 1, owing to the applicant’s cancellation thereof, there is insufficient antecedent basis for this limitation in the claim.

8. Claim 26 recites the limitation “the method according to Claim 6.” Because there is no Claim 6, owing to the applicant’s cancellation thereof, there is insufficient antecedent basis for this limitation in the claim.

9. The examiner notes that Claims 23-26 refer to earlier claims that have been cancelled by the applicant as detailed in the above 35 U.S.C. 112 rejections. For the purposes of providing a complete first action on the merits, the examiner has interpreted Claim 23 as referring back to Claim 22, not Claim 1; Claim 24 as referring back to Claim 23, not Claim 2; Claim 25 as referring back to Claim 22, not Claim 1; and Claim 26 as referring back to Claim 25, not Claim 6. The applicant is encouraged to make appropriate corrections to the instant claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 22 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,583,129 (hereinafter “Mazer”). The Mazer application teaches a method of “non-orally administering an androgenic steroid” to a woman in need thereof. (Claim 1). As defined in Mazer, “non-oral administration” includes the topical application of the steroid in “an appropriate carrier vehicle, such as a cream or ointment.” (C.5, L.66 – C.6 L 7). Mazer further enumerates the forms of androgenic steroid to include, *inter alia*, testosterone cypionate, testosterone phenylacetate, testosterone enanthate, testosterone buciclate, testosterone heptanoate, testosterone decanoate, testosterone caprate, testosterone isocaprate, and isomers thereof. (C.3 L.39-59). Mazer teaches, and therefore anticipates, all limitations of the instant Claim 22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazer in view of J. Shouls, et al, *Contact Allergy to Testosterone in an Androgen Patch: Control of Symptoms by Pre-application of Topical Corticosteroid*, 45 CONT. DERMATITIS 124 (2001) (hereinafter "Shouls"). Mazer teaches a method of non-oral application of testosterone esters as described in above paragraph 10, but does not particularly indicate testosterone phenyl propionate as one of the preferred esters for topical application. Shouls indicates that a composition comprising testosterone phenyl propionate has been used to provide transdermal testosterone therapy. (Pg. 124) Because both the testosterone derivatives of Mazer and the testosterone phenyl propionate of Shouls have been indicated as suitable for transdermal therapy in a patient in need thereof, it would have been prima facie obvious to one of ordinary skill in the art to combine the teaching of Shouls with that of Mazer to arrive at the invention of the instant claim.

12. Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazer in view of U.S. Patent Application Publication 2005/0101517 (hereinafter De Nijis) and U.S. Patent 6,004,566 (hereinafter Friedman).

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13. Mazer teaches a method of non-oral application of testosterone esters as described in above paragraph 10, but does not particularly indicate testosterone phenyl propionate in any concentration as one of the preferred esters for topical application, nor is an oil solution disclosed as a means of administering the ester.

14. De Nijis discloses that testosterone phenylpropionate is one of many testosterone esters available as part of an oily solution sold under the trademark Sustanon. (Para. 0005).

Furthermore, Friedman discloses a composition for topical application of a variety of pharmaceuticals, including steroids (C.2 L.62-63), in a vehicle comprising an oily liquid such as a medium chain triglyceride (MCT) having a chain length of about 8 to 12 carbons. (C.2, L.33-36). Additionally, Friedman teaches a steroid-containing composition wherein the steroid is present in a concentration of between 0.5 to 5%.

15. Because Friedman teaches a topical preparation of active ingredients including steroids, and De Nijis discloses that the use of testosterone phenylpropionate is well known in treating androgen insufficiency related disorders, it would have been prima facie obvious to one of skill in the art at the time the invention was made to combine their teachings to arrive at a composition comprising testosterone phenylpropionate in a MCT vehicle wherein the testosterone phenylpropionate comprised between 0.5 to 5% of the composition. It would have been further obvious to one of ordinary skill in the art to then use that composition in the method taught by Mazer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SMB

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161